PREMARKET NOTIFICATION 510(K) SUMMARY Page 1 of 2

1. Submitted By: Hudson Diagnostic Imaging LLC

610 Boulevard

Elmwood Park, NJ 07407

2. Contact Person: Dr. Martin E. Wendelken

3. Name Of Device/s:

a. Trade Names: Hudson 8000 Ultrasound Scanner*

Hudson 9000 Ultrasound Scanner**

b. Common Name: Ultrasound Scanner

c. Classification Name: Ultrasonic pulsed echo imaging system

FR No. 892,1560 Product Code: 90-IYN

4. Legally Marketed Device for which we are claiming substantial equivalence:

Scanner Trade Names: Mycolor 202 (Pico) Ultrasound Imaging System* Manufactured and Distributed by:

Medison America Inc. 11075 Knott Avenue Cypress, CA 90630

Scanner 510(k) Number: <u>K031552</u>

Scanner Trade Names: Aloka SSD-900 Ultrasound Imaging System**

Manufactured and Distributed By::

Aloka Co. Ltd.

10 Fairfield Boulevard Wallingford, CT 06492

Scanner 510(k) Numbers: K983879

Scanner Trade Names: Hudson 2020, 2040, and 2060 Ultrasound Imaging Systems
Distributed by:

Hudson Diagnostic Imaging LLC 610 Boulevard

Elmwood Park, NJ 07407

Scanner 510(k) Number: <u>K011284</u>

PREMARKET NOTIFICATION 510(K) SUMMARY Page 2 of 2

5. Description of the Device:

The Hudson 8000 & 9000 Imaging Systems are diagnostic ultrasound scanners which incorporates a proprietary method of imaging wounds both cavernous and non-cavernous types. The ultrasound scanners use linear array transducers (5—10 Mhz). The scanners are capable of imaging wounds including pressure ulcers which may invade and penetrate tissues as much as 6 cm in some areas of the body.

6. Intended Use of the Device:

High resolution ultrasound imaging of wounds

7. Summary of Technological Characteristics compared to Predicate Device:

The technological characteristic the predicate devices are equivalent. The incorporation of the Wendelken / Pope method of imaging wounds using diagnostic ultrasound along with predicate and equivalent ultrasound contact media provides for the imaging of wounds.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUN 1 0 2004

Dr. Martin E. Wendelken Official Correspondent Hudson Diagnostic Imaging L.L.C. 610 Boulevard ELMWOOD PARK NJ 07407

Re: K040926

Trade Name: Hudson 8000 and 9000 Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: April 7, 2004 Received: April 26, 2004

Dear Dr. Wendelken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Hudson 9000 Ultrasound System with UST-5524—7.5 40mm Linear Array Transducer and the following transducers intended for use with the Hudson 8000 Ultrasound System as described in your premarket notification:

HL 5-9ED 5-9 MHz Linear Array
C2-4ES Curved Linear Array
C3-7ED Curved Linear Array
HC2-5ED Curved Linear Array
EC4-9/10ED Endocavity Curved Linear Array
EC4-9ES Endocavity Curved Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Mancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Hudson 8000 Ultrasound System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Mode of Operation

Color

Dopoler

Arreitaide

Doppler

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Lumber <u>KO40 926</u>

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Other

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Intended Use; Diagnostic ultrasound Imaging or fluid flow analysis of the human body as follows:

PWD CWD

Ctrical Application

Prescription Use (Per 21 CFR 801.109)

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						 		Note 2 N	Note: 3,4,5,6
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				ļ		 		Note 2	Note 7
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				 	<u> </u>	 	- 	Note 2	+ -
	P	Р		↓		 	_		Note 3,6
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 		 ^		+	N	1		N-Note I	Note2,3,
1		<u> </u>		EDA:	E= adda	d under A	poendix F		
Note 1 opier,	: In c PWD	onjun Pow	ction er Doj	with W ppler; C	/endelker CWD/Col	or Dopple	er; CWD/ I	ower Dopple	tact media.
g for p	guida	nec of	Bios	py- No	ote 4: Tis	sue Harmo	onic (magi	ng 	
id, Pa	raThy	yroid,	Breas	st, Scro	tum, & P	enis in adu	ult, pediatr	ic and neonat	al patients
	23 I	w M n	rode	NoteH	ludson 80	100 Scanne	er is a rela	beled Mediso	n 11co Scal
ote 7:	Colc	11 145 11							
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Hudson HL 5-9ED-5-9 Mhz Linear Array Ultrasound Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode	of Operation		, , , , , , , , , , , , , , , , , , , 	
Civical Application	^	8	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color V=tocky Imaging	Combined (specify)	Other (epecify)
Ophrhalmic					 				<u> </u>	
Feed					<u> </u>				 	
Abdominal					 	ļ	<u> </u>		 	
Intraoperative (specify)	<u> </u>				<u> </u>	 	<u> </u>		 	
Intraoperative Neurological	<u> </u>			<u> </u>			 			
Pediatric		P	P	Р	↓	P	<u> </u>		P- Notes:	
Small Organ (specify)		Р	P	Р	↓	Р	ļ	ļ	P- Notes:	A.1.2,3
Nacretel Cophelic	<u> </u>				<u> </u>	ļ	 	ļ	 	
Adult Cophalic	<u> </u>			!	ļ	ļ	<u> </u>	 	ļ <u></u>	
Carrie	1_	↓			ļ		 -		-	
Transcrophognal	<u> </u>	<u> </u>			↓	<u> </u>	ļ <u>.</u>		 	
Trenerectal	<u> </u>	<u> </u>		<u> </u>		 	 	 	 	
Transcription	<u> </u>	<u> </u>		 	 	 	-	ļ <u> </u>	 	
Transurational	<u> </u>		ļ	↓	↓	 -	 	 	-	
By Processon Control		<u> </u>	ļ	<u> </u>	-		 		 	
Portpheral Vancator	1	P	l,	P	 	P -	 	 	P- Nores;	,2, 5
Laparoscopic	<u> </u>	1		 	 	ļ		 	<u> </u>	
Musiculo-electrical Conventional		P	P	P		P			P- Notes:	1,2, 3
Musculo-alcalabel Superficial	1	P	P	P	1	P			P- Notes:	1,2,3
Other (specify) Wounds	 	N		N	1	N			N-Note I	Note:2,

Other (specify) Wounds	N	N	N			N-Note I	Note: 2
N= new indication: P= t	previously d	leared by FC	A; E= added	under App	endix E		
Additional Comments:	n conjunctio	on with Wen	delken / Pope s	canning me	thod and o	ontact med	ıa.
Note A: Thyroid, parath	yroid, breas	t, scrotum an	d penis in adul	t, pediatric	and neona	tal patients	
Note 1; PWD/Color Do		_					
Note 3; CWD/ Color D		-			ssue Harm	onic imagir	າ <u>ຮ</u>
Note 5: The Hudson HL	, 5-9ED pro	be is a relabe	led Medison II	L 5-9 ED p	robe—Sec	K031552	
<u></u>	EASE DO HOT W	THE RELOW THE	ME-CONTINUE ON A	NOTHER PAGE 1	P NEETHED)		
	Corcure	es of CDRH, C	Man of Device E	is G.	Syen		and the second s
Prescription Use (Per 2	1 CFR 801.	109)	(Division S Division of and Radiol 510(X) Nur	Reprodu logical D	evices		i.

Hudson C2-4ES-Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended User Diagnostic ultrasound Imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	٨	8	м	PWO	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (epecify)		
Ophthalmic								<u> </u>	<u> </u>	ļ		
Fetal	<u> </u>	<u> </u>			<u> </u>							
Abdominal	 					<u> </u>				ļ <u> </u>		
Intrauparative (specify)	<u> </u>		ļ	1								
Interperative Neurological	<u> </u>				<u> </u>		<u> </u>		<u> </u>			
Pediatric									ļ	ļ		
Small Organ (apacity)		<u> </u>		<u> </u>					ļ			
Nametal Caphalic	<u> </u>											
Adult Cophalic					 					ļ		
Cardine Adult	1_	r	P	P_		Р	ļ		Note: 1	Note: 2		
Transsophegoal				 								
Transcental	<u> </u>	L								 		
Transaginal	<u> </u>	<u> </u>	<u> </u>	↓	 				<u> </u>			
Transcrational		<u> </u>	L	<u> </u>	<u> </u>					ļ		
Infrevencular			<u> </u>	<u> </u>					ļ	<u> </u>		
Peripheral Vanculer	<u> </u>			<u> </u>						-		
Laparoncopic	<u> </u>	<u> </u>		ļ	<u> </u>				↓			
Musiculo-alcufetal Conventional												
Musiculo-skeletal Superficial				<u> </u>	<u> </u>				<u> </u>	 		
Other (specify)		<u> </u>	<u> </u>	<u> </u>		<u> </u>	<u> </u>		<u> </u>	<u> </u>		
N= new Indication; P= Additional Comments; Note 1: PWD/Color De Note 2: Color M Mode	oppler								wer Dopple	<u> </u>		
Note 3: The Hudson C	2-4 1∜	s prot	e is a	relabe	led M	dison C2	-4 ES probe	See K0	31552			
		O MOT H	egic n	LOWTH	SUNE-C	CHITMLE ON	MOTHER PAGE	P NEEDED)				
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Prescription Use (Per 2	T CET	₹ 801	.109)				or Reprod ological [Abdomer	al,		

Hudson C3-7ED- Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer,

Mode of Operation

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Citrical Application	۸	6	M	PWD	CWD	Color Dappler	Ampitude Doppler	Cotor Velocity Imaging	Combined (qued fy)	Other (upwill y)
Ophthalmic					<u> </u>			ļ	ļ — —	
Fetal		P	P	P	<u> </u>	P		<u> </u>	Note: I	Note:2,3,4
Abduminal		P_	P	P	<u> </u>	P	ļ		Note: 1	Note:2,3,4
інтеарыльбен (врасіїу)				ļ	Ļ	 				
Intraperative Neurological	L			<u> </u>	ļ				<u> </u>	Note:2,3,4
Pediatric	<u> </u>	P	P	P	<u> </u>	P		ļ <u>.</u>	Note: I	Note:2,5,4
Smull Organ (specify)	<u> </u>	<u> </u>	<u> </u>	ļ	ļ		<u> </u>	 	 	
Necruital Capturilic	<u> </u>		<u> </u>	<u> </u>	ļ		 	ļ]	
Acut Cophelic	<u> </u>	<u> </u>	<u> </u>	 	ļ		ļ <u> </u>	<u> </u>	 	
Cardiec	<u> </u>	<u> </u>	<u> </u>	 	<u> </u>		<u> </u>	 		
Transasophagosal	↓	 	 	ļ	 -	 				
Transrectel		<u> </u>	ļ	<u> </u>	↓	ļ	ļ.———	 	-	
Transcaphal	<u> </u>		↓		ļ	ļ				
Transparediral	1_		 	1	1_	<u> </u>	<u> </u>	 	<u> </u>	
Intrevesquier	1	ļ	ļ	ļ	↓	<u> </u>	↓		 	├
Peripheral Vanezalar	ļ.,,		<u> </u>	↓	<u> </u>	ļ <u> </u>		<u> </u>	-	
Laparoscopic	<u> </u>	<u> </u>	ļ	1	 	<u> </u>	ļ			
Munculo-al-stated Committenal					<u> </u>	<u> </u>				<u> </u>
Musculo-skeletel Superficial	↓	↓	<u> </u>	<u> </u>	↓	<u> </u>	<u> </u>	 	 	
Other (specify)	<u> </u>	丄		<u>. </u>	<u></u>	<u></u>	1		<u> </u>	
N= new indication; P= Additional Comments: Note 1:PWD/Color De Note 2: Includes imagin Note 4: The Hudson C:	opplei g for	. PW guida	D/Pov	wer Do f biosp	oppler Y Not	CWD/Co	lor Doppler	, CWD/Po	Note 4: 31	
	LE40E O	DATT!	WATT B	DOW TH	BUNE . C	CONTINUE CON Of Davidoy E	ANOTHER PAGE	# H±20±07 >€)		
Prescription Use (Per 2	11 CF	R 801	(.1 0 9)	ı		Unvision Anvision and Rai	aum (b) sign-O n of Repridiologica	ff) / oductive I Device	, Abdomi s	nai,

510(k) Number K040926

Hudson C3-7ED-Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer,

						Mode	of Operation			
Citrical Application	A	6	•	PWD	CWD	Color Doppler	Amplitude Doppler	Cater Velocity Imaging	Combined (epecify)	(apacity)
Ophthalmic				ļ						-
Fertil		P	Р	P		Р			Note: I	Note:2,3,
Abdonéral	<u> </u>	P_	P	P		P			Note: 1	Note:2,3,
Intraperative (specify)	.	<u> </u>	!	<u> </u>			ļ		 	
Intraperative Neurological	<u> </u>			ļ. <u></u>						1 2 2 2
Pediatri:	<u> </u>	P	P	P		P			Note: 1	Note:2,3.
Smust Organ (specify)		<u> </u>	<u> </u>	Ļ		<u> </u>			 	
Nacnatel Cephylic	<u> </u>			<u> </u>	<u> </u>	ļ	<u></u>			
Adult Cophelic			<u> </u>	<u> </u>	<u> </u>				ļ	ļ
Cardino		<u> </u>			<u> </u>				ļ	
Tremenophageal			<u> </u>	ļ	<u> </u>					
Trianspectal					<u> </u>					
Transcripted	<u> </u>		<u> </u>	↓	<u> </u>					
Transparettral		<u> </u>		<u> </u>	ļ	<u> </u>		_	 	ļ
Intravascular		<u> </u>	<u> </u>	 	<u> </u>			ļ <u>.</u>		<u> </u>
Perlipheral Vancular	<u> </u>		ļ <u> </u>	<u> </u>	<u> </u>	 _			-	
Laparostoople		<u> </u>	<u> </u>	1	<u> </u>					<u> </u>
Musiculo-el-al-abili Conventional		_								
Musculo-skelntní Superficial	1_		<u> </u>		<u> </u>	 	<u> </u>		ļ	
Other (specify)			<u> </u>	<u> </u>	<u> </u>	<u>ii</u>		<u> </u>	<u> </u>	
N= new indication; P=	brevi	oneia	dear	ed by	FDA: I	E≂ ad ded	l under App	endix E		
Additional Comments:						<u></u> .				

Note 2: Includes imaging for guidance of biospy Note 3: Tissue Harmonic Imaging Note 4: 3D Imaging Note 4: The Hudson C3-7 CD probe is a relabeled Medison C3-7 ED probe—See K031552 PLEASE OR NOT WRITE BELOW THIS LINE - CONTINUE ON MOTHER PAGE IF Concurrence of CDRH, Office of Device/Disables (ODC) David a. Severan Cavistan Sign-Off) 4 Division of Reproductive, Abdominal, Prescription Use (Per 21 CFR 801.109) and Radiological Devices 510(k) Number K040926

Hudson HC2-5ED - Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	\bot					<u>مادينانا</u>	of Operation		,	
Clinical Application	^	В	ы	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (up-city)	Other (apacity)
Ophthalmic										
Fetal	↓	P	P	P_		<u> </u>	<u> </u>		Note: I	(ote:2,3,
Abdominal		Р	Р	P		P			Note: I	lote:2,3,
intraopunetive (specify)				ļ	<u> </u>	_	ļ			
Interoperative Neurological	↓	<u> </u>	<u> </u>		ļ			ļ		
Pediatric	┷	Р	P	P	ļ	Р			Note: 1	Note:2.3,
Small Organ (specify)	↓				ļ	ļ	ļ <u> </u>			
Naoradal Caphelic	Щ.	<u> </u>	<u> </u>	 	ļ					
Adult Cophalic	\downarrow	ļ	 	<u> </u>			<u> </u>		ļ	
Cardioc	 	 					ļ			
Transcouplingsel	↓	 	<u> </u>	 	ļ	 			1	
Trimerectel	 	1	 	<u> </u>	<u> </u>		ļ		<u> </u>	
Transveginal		 		ļ	 				 	
Transactional	 	₩-		 				<u> </u>		
Introvescular	 -	}	ļ	 	<u> </u>				 	-
Peripheral Vascular	 -	ļ	<u> </u>	.	├ ─	<u> </u>	<u> </u>			
Laparoscopic	 	├ ─	 	↓		ļ				
Musculo-electrical Conventional						ļ				
Musculo-skeletal Superficial	 	 	<u> </u>	↓	ļ <u> </u>	<u> </u>		ļ	ļ	}
Other (specify)	<u> </u>		<u> </u>	<u> </u>		<u> </u>		<u> </u>		
N= new Indication; P= Additional Comments: Note 1:PWD/Color De Note 2: Includes imagi	oppler, ing for	PWI:)/Pow	er Dog of blosp	opler, C	:WD/Cole te 3: Tissu	or Doppler, uc Harmoni	CWD/Pow	Note 4: 3	D Imagin
Note 5: The Hudson H	U2-5 F	D pro	obe is	a relat	peled N	Acdison H	IC2 2-5 EO	probe Sc	e K031552	
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					Office	A	valuation (00		n	
Prescription Use (Per 2	ti CFF	₹ 801	.109)			agan o	Reprodu logical D	uctive, A	bdomina	Í,

Hudson EC4-9/10ED- Endocavity Curved Linear Array

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	<u> </u>				· · · · · ·	Mode	of Operation		,	
Clinical Application	^	В	w	PWD	cwo	Cotor Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (up=cify)	Other (specify)
Ophthalmic	<u> </u>		<u> </u>	ļ						<u> </u>
Feed										
Abdominal				<u> </u>						
Intraopurative (specify)	<u> </u>								 	<u> </u>
Interoperative Neurological				<u> </u>		_				
Peclaric	<u> </u>									
Small Organ (specify)	<u> </u>			<u> </u>						<u> </u>
Necretal Captudic	<u> </u>					<u>-</u>				
Adult Caphalic		<u> </u>		<u> </u>						<u> </u>
Cardioc	 	<u> </u>	ļ							
Transesophageal	ļ	L	<u> </u>		ļ					
Transmictal	ļ	P	P	P		Р			Note: 1	Note:24
Transveginal		P	P	P_		P			Note: I	Note:2,3
Transcription	<u> </u>		L	 						
and several states	<u> </u>			ļ						
Podpharal Vancular	<u> </u>			<u> </u>						<u> </u>
Сириговорис										
Musiculo-skeletel Conventional								·		
Munculo-skeletal Superficial			<u> </u>	<u> </u>						
Other (specify)		1	1]					}

Note: 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler, Note: 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler, Note: 2: Includes imaging for guidance of biospy

Note: 3: Includes intertility monitoring of follicle development:

Note: 4: 3D Imaging

Note: 5: The Hudson EC 4-9/10ED probe is a relabeled Medison EC 4-9/10 ED probe: See K031552

PLEASE CONDITION OF CONTROL OF PROBLEM (OPE)

Consumers of Costs, Office of Device Problem (OPE)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number: K04-092-U

Hudson EC4-9ES- Endocavity Curved Linear Array

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound Imaging or fluid flow analysis of the human body as follows:

Clinical Application	^	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (upacity)	Other (specify)
Ophthalmic										
Feld		L.,	ļ		ļ					
Abdominal			<u> </u>	<u> </u>				 		
Introoperative (specify)		ļ	ļ	<u> </u>						
Interconstitute Neurological	<u> </u>	<u> </u>	ļ	<u> </u>		 			ļ	
Pediatric		<u> </u>	ļ	_				<u> </u>		
Small Organ (specify)	ļ	ļ	ļ	 	ļ		ļ	 		
Neonatel Caphalic	<u> </u>	 	 	 	 	 				
Adult Cephalic	<u> </u>	 	L –	 -	 	<u> </u>	ļ			
Cardisc	 	 	<u> </u>	ļ	 		 		<u> </u>	
Transscophageal		 	 		 -	1 15	 	 	Note: 1	Note:2,4
Transmittel	 -	P	P	P	-	P		ļ	Note: 1	Note:2,3,4
Tramonginal		P	P	P	 	P	<u> </u>	 	14000.7	1000.2.2.
Transuretival	ļ	ļ	 	 	ļ.	ł —			 	
Intravisional	 	-	 	 	 	<u> </u>	 	-	<u> </u>	
Peripheral Visitouler	ļ	-	-	 	╀	 	1	 	 	
Lepennoopic	<u> </u>	<u> </u>	 	┼—	╁		 	 	 	
Musiculo-skeletel Conventional			<u> </u>	<u> </u>	<u> </u>			<u> </u>		
Musiculo-rikalebil Superficial	 .	↓	<u> </u>	↓	├	-	<u> </u>	 	 	
Other (epocity)	<u></u>	<u> </u>	ــــــــــــــــــــــــــــــــــــــ	ل		-	1 4	madis E	<u>!</u>	<u> </u>
N= new indication; P= Additional Comments:									Do-ato	
Note 1:PWD/Color De						CWD/Co	<u>ior Doppler</u>	, CWD/Po	wer Dobbie	<u> </u>
Note 2: Includes imagin									•	·
Note 3: Includes inferti								ote 4: 3D I		
Note 5: The Hudson EC									(031552	<u> </u>
	USAGE O	TON OT	MPETE E	CORP	Office	of Device !	ANOTHER PACE Evaluation (CE	DE)	 -	
Prescription Use (Per 2						Ya Vision o	und (d., 	Seyur uctive, A		ić,
					- 5-4	0(%)	mber 1	K0409	726	

Hudson 9000 Ultrasound System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*	Mode of Operation												
Ctinical Application	A	B	M	PWD	CWD	Color Doppier	Amplitude Doppler	Color Velocity Imaging	Combined (epacify)	Other (specify)			
Ophthalmic		Р	P						B/M				
	_	-بر	य	1					В/М				
Federal		1	ין	+	1	 			B/M				
Abdominal		P -	٦-	 	 	-	 		В/М				
Introperates		17	- 1 -	┼─	 		 	 	B/M	1			
Intercological		P	P	-	-				В/М	 			
Pediatric		P	P	 	 		 		B/M	Note 2			
Small Organ (apacify)	ļ	<u>'</u>	L		ļ	}		<u> </u>	B/M	Note 2			
Naonatri Cephalic		P	P	1	!	}							
Adult Cophalic		P	P	<u> </u>	<u> </u>				B/M				
Cardina Pediatric			<u> </u>		<u></u>		ļ <u>.</u>	_					
Transcriophagoal		P	P	I		i			B/M	ļ			
Transactal		P	12				ļ <u> </u>		B/M	 			
Fransvaginal					ļ		<u> </u>			 			
Transprotext			<u> </u>		1	ļ	<u> </u>	<u> </u>		 			
Interescent		P	P		<u></u>			<u> </u>	В/М	ļ			
Poripheral Vancular	1	P	P		I		<u> </u>		B/M	ļ			
Lapwoncopic		P	P					<u> </u>	B/M	<u> </u>			
Microsto state of Conventional													
Museuko-akadental SUBUNUSA						<u> </u>		ļ	ļ	 			
Oner (specify) N= new Indication; P=		N	N				<u> </u>		B/M	Note 1			

Note 1: In conjunction with Wendelken / Pope scanning method and contact media.

Note 2: Thyroid, Parathyroid, Breast, Scrotum, Penis in adult, Pediatric and Neonatal Patents

Note 3: The Hudson 900 Ultrasound System is a relabeled Aloka 900 Ultrasound System | See K983879

| Prescription Use (Per 21 CFR 801.109) | Division of Reproductive, Abdominal, and Radiological Devices | 510(k) Number | K040926

Hudson UST-5524-7.5 40mm Linear Array Ultrasound Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode	of Operation			
Uhlad Application	۸	в	ᆈ	PWO	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Splinthalirric					-					
	<u> </u>			 	 		ļ		 	<u></u>
Undominal	L			<u> </u>			<u> </u>		 	
пізнорнийна (вресіў)				ļ	↓				 	
nteroperative Neurological				<u> </u>	<u> </u>				<u> </u>	
Pediatric	<u> </u>			1	<u> </u>		ļ		 	
Small Organ (specify)		Р	P		<u> </u>				B/M_	Note:
Nacrustel Caphalic				Ι	<u> </u>		<u> </u>	<u> </u>	1	
Adult Cophalic							<u> </u>			
Cardiuc							ļ			
Transacophagnal		<u> </u>		ļ	↓	_	ļ <u>-</u>		 	
[ranarectel	<u> </u>	↓		ļ	_	 	 	 	 	
Transactions	<u> </u>			↓	<u> </u>	<u> </u>	 	 	 	
Transurethral	<u> </u>		L	↓	<u> </u>	ļ	 	 		,
Infrancioscular	<u> </u>	<u> </u>				<u> </u>			 	
Periphical Vancular		<u> </u>	P					<u> </u>	B/M	
Laparoecopic			L_		<u> </u>	<u> </u>	 	ļ	-	
Municulo-eliment Conventional					<u> </u>	ļ				
Musculo-skelntri Superficial		<u> </u>	<u> </u>	↓	↓	 	 			<u> </u>
Other (specify) Wounds	1	N	N	1	<u> </u>		<u> </u>	<u> </u>	N= R/M	Note I
N= new indication; P= Additional Comments: Note I: In conjunctio										

Conventional		\longrightarrow		 	+	·			
Musculo-rikelintrii Superficiali				 	- -				
Other (specify) Wounds	N	N		<u> </u>	<u> </u>		<u> </u>	R/M	Note I
N= new indication; P= pre	viously (deere	by FOA:	E= edde	d under A	ppendix E			
Additional Comments:			·						
Note I: In conjunction w	ith Wene	delken	/ Pope sea	ming met	hod and c	intact medi	a.		
Note 2: Thyroid, Parathy	roid, Bro	ast, Sc	rotum, Pen	is in adul	t, Pediatri	and Noon	stal Pate	ents	
Note 3: The Hudson US'I	'-5524 pi	obe is	a relabeled	Aloka U	JST-5524	probeSee	K9838	379	
GE 544		ente sel	OW THIS LINE -	CONTRILE OF	ANOTHER PA	DE IF NEEDED)			
(//25	Concum	nca ef	COOL OF	and Danisland	Personal Control	ape)			
				Z) jih	wit M.	hyer	an		
			(D	ivision :	Sig ~Off) /			
Prescription Use (Per 21 C	ጎርጭ ድስተ	109)	Ďi	งเออก ด	t Repro	ductive,	Abdor	minal	,
Prescription use (For 2.1)	A 1. 00 !	. 1007	ar	d Radio	ological	Devices	1	,	
			51	0(k) Nu	ımber_	KO40	926	<u> </u>	